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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,719	07/02/2003	Jeffrey Nool	P1381.00 (PERCUS.179A)	3778

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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12/28/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/612,719

Applicant(s)

NOOL ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10 and 42-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10 and 42-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 10/09/2007 in which claim 1 was amended and new claims 42-57 were added. Currently claims 1-7, 9-10 and 42-57 are pending for examination in this application.

Claim Objections

Claim 45 is objected to because of the following informalities: Regarding claim 45, Examiner asserts that the filter is only functional claimed in the preamble and then further recited in the body of the claim and further dependant claims. Examiner requests Applicant either positively recite the filter with antecedent basis or reference the filter as a functional limitation throughout the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 51 and 55, are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (5,405,341). Martin discloses a catheter with multiple lumens.

Regarding claims 1, 3-4, 51 and 55, Martin discloses an aspiration catheter (20), comprising: an elongate catheter body (21) having proximal and distal ends; an aspiration lumen (46) with a plurality of ports (48, 52) and angled tip (146) extending longitudinally through the elongate catheter body between the catheter body proximal

end, the aspiration port being sized for aspirating particles from a blood vessel; and a guidewire lumen (44) being adapted for slidably receiving a guidewire and extending longitudinally through at least a portion of the elongate catheter body adjacent the aspiration lumen (Figures 1 and 4), from a proximal port to a distal port opening to the exterior of the elongate catheter body; and wherein the elongate catheter body includes a distal segment (26) wherein the aspiration lumen extends distally beyond the distal port of the guidewire lumen, the aspiration lumen within the distal segment being configured to convey embolic material proximally from the blood vessel upon exposure to a source of negative pressure (Figures 1-7).

Claim Rejections - 35 USC § 102

Claims 1, 3, 51 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Melker et al. (5,328,480). Melker et al. discloses a vascular wire guide introducer and method of use.

Regarding claims 1, 3, 51 and 55, Melker et al. discloses an aspiration catheter (10), comprising: an elongate catheter body (20) having proximal and distal ends; an aspiration lumen (15) and angled tip (12) extending longitudinally through the elongate catheter body between the catheter body proximal end, the aspiration port being sized for aspirating particles from a blood vessel; and a guidewire lumen (15) being adapted for slidably receiving a guidewire and extending longitudinally through at least a portion of the elongate catheter body adjacent the aspiration lumen (Figures 1 and 2), from a proximal port to a distal port opening to the exterior of the elongate catheter body; and wherein the elongate catheter body includes a distal segment (19) wherein the

aspiration lumen extends distally beyond the distal port of the guidewire lumen, the aspiration lumen within the distal segment being configured to convey embolic material proximally from the blood vessel upon exposure to a source of negative pressure (Figures 1-4).

Claim Rejections - 35 USC § 102

Claims 1, 44, 51, and 52-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bagaosian et al. (6,152,909). Bagaosian et al. discloses an aspiration system and method of use.

Regarding claims 1, 44, 51 and 52-53, Bagaosian et al. discloses an aspiration catheter (10), comprising: an elongate catheter body (20) having proximal and distal ends; an aspiration lumen (15) and angled tip (12) extending longitudinally through the elongate catheter body between the catheter body proximal end, the aspiration port being sized for aspirating particles from a blood vessel; and a guidewire lumen (15) being adapted for slidably receiving a guidewire and extending longitudinally through at least a portion of the elongate catheter body adjacent the aspiration lumen (Figures 1 and 2), from a proximal port to a distal port opening to the exterior of the elongate catheter body; and wherein the elongate catheter body includes a distal segment with radiopaque marker (19) wherein the aspiration lumen extends distally beyond the distal port of the guidewire lumen, the aspiration lumen within the distal segment being configured to convey embolic material proximally from the blood vessel upon exposure to a source of negative pressure (160) (Figures 1-4). Bagaosian et al. additionally discloses

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 6-7, and 43 are rejected under 35 U.S.C 103(a) as being unpatentable over Martin (or Bagaoisan et al. or Melker et al.). Martin (or Bagaoisan et al. or Melker et al.) discloses the claimed invention except for the specific catheter lengths and interior diameter dimensions.

Regarding claims 2, 6-7 and 43, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the catheters to the dimensions as claimed by Applicant, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art, especially in the medical device field of catheters in which dimension are varied to coincide with patient size, and the vasculature being accessed, see *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim Rejections - 35 USC § 103

Claims 5, 42 and 53-55 are rejected under 35 U.S.C 103(a) as being unpatentable over Martin (or Melker et al.) in view of Bagaosian et al. Martin (or Melker et al.) meets the claim limitations as described above except for the specific guidewire lumen location, and cross sectional geometry.

However, Bagaosian et al. teaches an aspiration system and method of use.

Regarding claims 5, 42 and 53-55, Bagaosian et al. teaches an aspiration catheter (Figure 5) with an angled guidewire lumen (40) only present on the distal end thereof with the guidewire lumen cross sectional area less than that of an angled aspiration lumen (42) cross section (Figure 7B).

At the time of the invention, it would have been obvious to the catheter of Martin (or Melker et al.) with the guidewire lumen of Bagaosian et al. to provide an alternate structure which has beneficial rapid exchange properties over a dedicated hub channel guidewire lumen. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Bagaosian et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 9-10, 45-50 and 56-57 are rejected under 35 U.S.C 103(a) as being unpatentable over Bagaosian et al. in view of Tsugita (6,168,579). Bagaosian et al. meets the claim limitations as described above except for the additional irrigation lumen, therapy device and porous filter attached to the distal of the guidewire.

However, Tsugita teaches a filter flush system and methods of use.

Regarding claims 9-10, 45-50 and 56-57, Tsugita teaches an aspiration catheter (Figures 2B, and 3B-3C) in which an irrigation lumen (42, 55, 35) and a guidewire with a porous filter member (28, 20) is attached to a guidewire (10).

At the time of the invention, it would have been obvious to add the additional lumen and filter member of Tsugita to the system of Bagaosian et al. in order to capture embolic particles that may dislodge during the surgical procedure. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Tsgutia (cols 1-2).

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9-10, and 42-57 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

12/19/22




Christopher D. Koharski
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